Spurious drugs

1271. SHRI NANDI YELLAIAH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the fact that market in the country is being flooded with spurious medicines and drugs;

(b) if so, the details of the spurious medicine and drug manufacturers identified so far in the country, State-wise;

(c) the details of the action taken so far in punishing and prosecuting such manufacturers, State-wise;

(d) the details of the remedial measures taken so far in preventing the entry of spurious medicines and drugs at distributors and retail medical shops level; and

(e) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) As per feedback available from State Drugs Control Administrations, 36947, 34574 and 36314 drug samples were tested during the period 2000-2001, 2001-2002 and 2002-2003, out of which 112,98 and 125 samples respectively were found purious. Thus, it does not appear that market in India is being flooded with spurious drugs.

(b) and (c) Under the Drugs & Cosmetics Act, 1940 and rules there under, the responsibility for regulating manufacture and sale of drugs including taking administrative and legal action against the manufacturers rests with the State Governments. Based on the gravity of the offence detected, necessary punitive action under the said Act and Rules is taken against manufacturers for such categories of drugs by the concerned Drugs Controllers. In view of this, specific details of spurious drug detected etc. together with their identified manufacturers are, not maintained centrally.

(d) and (e): Under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder, the responsibility for regulating manufacture and sale of drugs including monitoring their quality is vested with the State Government. The State Governments are advised from time to time to gear up their enforcement machinery to detect and unearth spurious/

fake drugs moving in the inter-state commerce as well as to provide and strengthen their regulatory infrastructure; to establish their own State level testing labs. to ensure speedy analysis of drug samples for which they are provided assistance to strengthen and augment their labs and infrastructure facilities. The State Governments have also been advised to keep strict surveillance over the suspected dealers; collection of survey samples under NSQD programme; constitution/reactivation of state drug advisory committees in which various trade and industry association as well as consumer associations can file representations; establishment of separate intelligence-cum-legal cell; development of efficient communication facilities and recall procedures; engaging experienced counsel for fighting spurious drug cases etc.

Government of India has taken the following initiatives to tackle the problem of spurious drugs:-

i) Detailed guidelines in respect of strategies required to be adopted for efficient surveillance over the movement of spurious drugs were issued to states in November 17, 1999 to ensure focused surveiuance over manufacture and sale of spurious drugs.

ii) The issue of alleged sale of spurious drugs was taken up by Union Health Minister with State Health Ministers in the 7th Conference of Central Council of Health (CCH) & FW held on 12-13 July, 2001. CCH resolved that in order to address issues relating to the increasing reports of spurious drugs/counterfeit drug, special attention requires to be given to monitor and unearth such illegal activities by constituting a separate intelligence-cum-legal cell in the respective drug control organization and in seeking cooperation of the pharma industry, trade as well as the police.

iii) Department of Health constituted a broad based Committee under the Chairmanship of DGHS in July, 2001 to examine issue concerning the problem of spurious drugs. The observation and recommendations of this Committee have been circulated on September 16, 2002 to all State Drugs Controllers for their information and necessary action in the matter.

iv) Union Minister of Health and Family Welfare had specifically written to all Chief Ministers on Oct., 8, 2002 on the issue of spurious

drugs, seeking their personal intervention to ensure that adequate measures are taken in each State to vigorously pursue the strategies needed to preclude any possibility of menace of spurious produces so as to collectively ensure its total eradication.

v) A meeting of Health Ministers and Senior Officials of 13 major States of the country was convened by Union Minister of health and Family Welfare on 12th November, 2002 to ensure concerted action to check and possible movement of spurious drugs in the country and to involve all state holders to fight this menace. Suggestions/views which emerged out of discussion were forwarded on Jan., 8, 2003 to all the State Governments for their information and necesary action. One of the recommendations which emerged outcome of discussion, was enactment of "The Gujarat Prevention of Anti-social Activities Act, 1985(PASA)" by the State Governments for deterrent action against offenders.

vi) In order to increase the number of drug samples tested in the country and to bring down the reporting time to less than a month as against 3 to 6 month presently being taken by many laboratories, a comprehenive plan has been undertaken by Central Government under a capacity building project through World Bank assistance.

vii) In order to ensure speedy information exchange and networking of all States and Central Drug Control Offices and Laboratories, computerization project has been undertaken by Central Government.

viii) A specialized training programme for drugs control officers of all State Governments responsible for keeping surveillance over possible movement of spurious drug has been formulated and was conducted from 24-27 June, 2003 by Central Government in cooperation with FDA, Maharashtra at Mumbai. 26 drugs control officers from different States had attended the training programme at FDA, Mumbai on intelligence, investigation, drafting of complaint and effective follow up of the cases filed in the court of law.

ix) Government of India have constituted a Committee of experts on January 27, 2003 under the Chairmanship of Dr. R.A. Mashelkar, Director General, Council for Scientific and Industrial Research

(CSIR) to undertake a comprehensive review of the drugs regulatory system in the country including the problem of spurious and substandard drugs and recommend remedial measures to deal with this problem effectively. The Government has intiated steps to study the measures recommended in the report submitted by the expert committee.

Side effects of drugs

1272. SHRI EKANATH K. THAKUR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the pharmaceutical companies in the country fail to update doctors on new side effects of widely used drugs by not updating the information on package inserts;

(b) whether it was found that though product insert serve as a guide to the prescribe and the patient, there is no mention of last update and also on warnings issued by the drug regulators like the USFDA; and

(c) if so, the steps Government propose to take to emphasize on updates by pharmaceutical companies to ensure the safety of patients?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) to (c) While granting the New Drug approval, under Rule 122 A/B, the pharmaceutical companies are required to follow the condition regarding adaptation of package insert, carton & label. Also the company has to state if any restriction have been placed on the use of drug in any other country e.g. dosage limit, exclusion of certain age group, warning about adverse drug reaction etc. as per item 10 in Schedule Y of Drugs and Cosmetics Rules.

It is however, the responsibility of drug manufactures to keep the Medical Community informed about the side effects of drug marketed by them and also to update their package insert and product information regularly.

The package insert is issued by Doctors in order to ensure that prescription drug information is balanced and accurately communicated.